K082213

OSSTEM Implant Co., Ltd.
#507-8 Geoje3-Dong Yeonje-Gu Busan, 611-804 Republic of Korea
Tel: +82 51 850-2500 Fax: +82 51 850-4341 www.osstem.com

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: July 30, 2008

1. Company and Correspondent making the submission:

- Submitter's Name :	OSSTEM Implant Co., Ltd.
- Address :	#507-8 Geoje3-Dong Yeonje-Gu Busan, 611-804, Republic of Korea
- Contact :	Mr. JongHyuk Seo

2. Device :

Trade or (Proprietary) Name :	GS III Fixture System
Common or usual name :	Dental Implant
Classification Name :	Endosseous Dental Implant 21CFR872.3640 Class II DZE

3. Predicate Device :
The HG II Fixture System, Osstem Implant Co., Ltd, K080744

4. Description :
The GS III Fixture System is a dental implant made of titanium metal intended to be surgically placed in the bone of the upper or lower jaw arches.

The GS III Fixture System is similar to other commercially available products based on the intended use, the technology used, the claims, the material composition employed and performance characteristics.

The GS III Fixture System is substantially equivalent in design, function and intended use to the HG II Fixture System(K080744) of Osstem Implant Co., Ltd.

5. Indication for use :
The GS III Fixture System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained,

screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework.
The GS III Fixture System is for single and two stage surgical procedures. It is not for immediate load.

6. Review :
The GS III Fixture System has same material and indication for use and similar design and technological characteristics as the predicate device.

The GS III Fixture System has been subjected to safety, performance, and product validations prior to release. Safety tests including biocompatibility have been performed to ensure the devices comply with the applicable International and US regulations.

7. Conclusion :
Based on the information provided in this premarket notification Osstem concludes that the GS III Fixture System is safe and effective and substantially equivalent to the predicate device as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 4 2008

OSSTEM Implant Company, Limited
C/o Mr. MinJoo Kim
Manager
OSSTEM, Incorporated
85 Ben Fairless Drive
Fairless Hills, Pennsylvania 19030

Re: K082213
Trade/Device Name: GS III Fixture System
Regulation Number: 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: October 1, 2008
Received: October 6, 2008

Dear Mr. Kim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu S. Lin, Ph. D
Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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510(k) Number K _____

Device Name: GS III Fixture System

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Prescription Use___X_____ (Per 21CFR801 Subpart D) OR Over-The-Counter Use _____. (Per 21CFR807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K052213